UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

UNITED STATES *ex rel*. LIUBOV SKIBO, et al., Plaintiffs, v. GREER LABORATORIES, INC., et al., Defendants.	CIVIL ACTION NO. 5:13-cv-110 **Request for Oral Argument**

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANT GREER LABORATORIES, INC.'S MOTION TO DISMISS RELATORS' AMENDED COMPLAINT PURSUANT TO RULES 8, 9(B), AND 12(B)(6)

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Defendant Greer Laboratories, Inc. ("Greer") files this Reply to address the most serious shortcomings in Relators' Opposition to Greer's Motion to Dismiss (the "Opposition").[1] Notwithstanding Relators' creative attempts to re-plead their claims and obscure their essential deficiencies, the conclusion remains that their allegations fall far short of well-established pleading requirements necessary to pursue their False Claims Act ("FCA") claims.

PRELIMINARY STATEMENT

In tacit acknowledgement of the deficiency of the allegations in their Amended Complaint, Relators improperly attempt to supplement those allegations in the Opposition. For example, for the first time Relators now assert that the Court can "infer" the existence of claims for reimbursement for custom mixes from irrelevant market share data. (Opp. at 9-12). It is well-settled, however, that a plaintiff "is bound by the allegations contained in its complaint and cannot, through the use of motion briefs, amend the complaint." *Zachair Ltd. v. Driggs*, 965 F. Supp. 741, 748 n.4 (D. Md. 1997). "To hold otherwise would mean that a party could unilaterally amend a complaint at will, even without filing an amendment, and simply by raising a point in a brief."[2] *Hongda Chem. USA, LLC v. Shangyu Sunfit Chem. Co.*, No. 1:12CV1146, 2016 U.S. Dist. LEXIS 20501, at *24 (M.D.N.C. Feb. 18, 2016). Accordingly, the Court should ignore these newly proffered allegations in considering Greer's Motion to Dismiss.

Whether or not this Court considers these new allegations, Relators fail to meet their burden under FRCP 9(b) to allege with particularity two essential elements of an FCA claim: (i) that Greer submitted or caused to be submitted objectively false claims for payment to the government; and (ii) had such claims been submitted, that Greer acted with the requisite intent in

[1] Greer's Memorandum of Law in Support of its Motion to Dismiss ("Moving Brief") is cited as ("Mov."). The Opposition is cited as ("Opp."). All references to exhibits refer to Relators' exhibits submitted in support of the Opposition.

[2] Relators' inclusion of their "motion" for leave to amend in the Opposition also violates LCvR 7.1(C)(2).

light of the industry-wide understanding that custom mixes did not require separate licenses. Notwithstanding Relators' efforts to translate FDA's recent clarification of this issue into prior fraud by Greer, Greer's good faith belief that no separate license was required forecloses their FCA claims.

ARGUMENT

I. Relators Fail to Plausibly Allege That Greer Submitted Claims for Payment to the Government.

It is well-settled that "[e]vidence of an actual false claim is 'the *sine qua non*' of a [FCA] violation." *United States ex rel. Dugan*, No. 2003-3485, 2009 U.S. Dist. LEXIS 89701, at *14 (D. Md. Sept. 29, 2009) (citation omitted). Relators argue that they have satisfied this element of their FCA claim because: (i) "Greer sold numerous Custom Mixes directly to" Offutt Air Force Base ("OAFB"), and (ii) "Greer's custom mixes account for a substantial portion of the *overall* U.S. market for allergen immunotherapy, for which Medicare has paid hundreds of millions of dollars." (Opp. at 7, 9-11). Both points miss the mark because neither provides the level of particularity required for fraud claims under FRCP 9(b), relying instead on far-fetched inferences that Relators ask the Court to make in denying Greer's motion. This is not the law. An FCA plaintiff cannot satisfy FRCP 9(b) by "alleg[ing] simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." *United States ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 457 (4th Cir. 2013);[3] *United States ex rel. Lambert v. Elliott Contr., Inc.*, No. 1:13-1106, 2015 U.S. Dist. LEXIS 29722, at *31 (S.D. W.Va. Mar. 11, 2015)

[3] Relators' reliance on *Nathan* turns the Fourth Circuit's strict application of FRCP 9(b) in that case on its head. Relators cite to an argument by the relator in *Nathan* that the Court could infer a false claim in the absence of specific allegations, an argument the Court rejected because the supporting cases involved deliberately fraudulent schemes, such as doctors billing for services that were never provided. *Id.* As in *Nathan*, those cases have no application here.

("[relators cannot] allege that defendants violated the [FCA], yet plead no information detailing a *claim* made to the government"). Rather, Relators must allege the "who, what, when, where, and how of the alleged fraud." *Hedley v. Abhe & Svoboda, Inc.*, No. 14-2935, 2015 U.S. Dist. LEXIS 100070, at *10 (D. Md. July 31, 2015).

A. Relators Do Not Adequately Allege That Greer Sold Custom Mixes to OAFB.

Relators' allegations of Greer's supposed sales to OAFB fail for two reasons. First, the allegations rest entirely upon Relators' Exhibit 1, an undated and unauthenticated document which provides no information about custom mix sales. *In re Wachovia Corp.*, No. 3:09cv262, 2010 U.S. Dist. LEXIS 79971, at *17 n.4 (W.D.N.C. Aug. 6, 2010) (court may not consider documents relied upon in the complaint if their authenticity is disputed). Indeed, Exhibit 1 lacks the most basic information typically associated with a sale, including the dates of supposed orders, order numbers, prices, quantities, shipping information or customer ID numbers. As a matter of law, this list is incapable of supporting an allegation that Greer submitted a claim to the government. *United States ex rel. Rector v. Bon Secours Richmond Health Corp.*, No. 3:11-CV-38, 2014 U.S. Dist. LEXIS 52161, at *28-29 (E.D. Va. Apr. 14, 2014) (patient log was "not enough to plausibly allege that the procedures necessarily took place or that the Government was billed by [the facility]"); *United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 352-53 (D. Mass. 2011) (dismissing complaint that "conclusorily referenced" sales to government agencies but did not tie them to a particular claim).

Second, Relators' new allegations reciting general statistics about Greer's *total* allergen immunotherapy sales in Nebraska in 2009 say nothing about whether Greer sold *custom mixes* in Nebraska in 2009, let alone to OAFB. The Court cannot and should not draw the significant inferences necessary to conclude from these vague allegations that Greer submitted a claim to the government. *United States v. Grifols Biologicals, Inc.*, No. 07-3176, 2010 U.S. Dist. LEXIS

68775, at *18 (D. Md. July 9, 2010) ("We cannot make assumptions about a [FCA] defendant's submission of actual claims to the Government without stripping all meaning from Rule 9(b)'s requirement of specificity"); *United States v. Riverside*, No. 4:11cv109, 2015 U.S. Dist. LEXIS 37134, *42-43 (E.D. Va. Mar. 23, 2015) (dismissing complaint where relators alleged that billing system automatically overcharged for medication pathways, but failed to identify "any *specific* excessive bills" submitted to government payors).

B. Relators' New Allegations Regarding Greer's Market Share Do Not Satisfy Their Obligation to Identify Specific Claims.

Relators' generalized claims about other unidentified entities to which Greer supposedly sold custom mixes fare even worse. For the first time, Relators now assert that "there is a highly plausible inference" that false claims were presented for Greer's custom mixes based on: (i) its "30%-52% share of the overall U.S. market for allergen immunotherapy," (ii) the fact that over half of Greer's "bulk allergenic extract lots were custom mixes,"[4] and that (iii) "Medicare has historically reimbursed hundreds of millions of dollars for allergen immunotherapy." (Opp. at 10-11). This attempt to shore up the insufficient allegations of their Amended Complaint with pure speculation fails. Far from providing the required "who, what, when, where and how" of the alleged claim for payment, these allegations do not even provide the "who." *Hedley*, 2015 U.S. Dist. LEXIS 100070, at *10. Moreover, market share data about Greer's allergy immunotherapy business as *a whole* does not speak to Greer's custom mix business or claims for custom mixes. *See Lambert*, 2015 U.S. Dist. LEXIS 29722, at *30 (dismissing claim because "complaint presume[d] that defendants did indeed present a claim to the Government for

[4] Relators fail to explain how one can extrapolate information about sales from data about lots, because they cannot. This Court should not presume, simply because Relators say so, that the percentage of custom mix sales mirrors the percentage of custom mix lots. Although not relevant to Greer's Motion, Relators grossly overstate Greer's market share for custom mixes.

payment because they should have or must have presented a claim"). Citing market statistics is simply not an adequate substitute for alleging with particularity specific claims for payment from the government. *Riverside*, 2015 U.S. Dist. LEXIS 37134, at *39 n.7 ("[court] cannot plausibly infer, from only the general statistics that Government Payors covered [20-30%] of Defendants' patients, that Defendants submitted any [claims] to Government Payors"). Accordingly, Relators fail to satisfy FRCP 9(b).

II. Relators Do Not Establish That Greer Knowingly Submitted An Objectively False Claim.

Relators' attempt to create a factual dispute regarding the regulatory history only serves to prove Greer's point—that prior to 2015, Greer (and the rest of the industry) did not believe that separate licenses for custom mixes were required. *See United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 288 (D.C. Cir. 2015) (FCA does not reach those "claims made based on reasonable but erroneous interpretations of a defendant's legal obligations"). This negates any inference of Greer's intent to defraud FDA or submit objectively false claims, both essential elements of Relators' FCA claim. *United States v. Triple Canopy, Inc.*, 775 F.3d 628, 634 (4th Cir. 2015).

A. Relators Have Not Alleged That Any Claim Submitted By Greer Was Objectively False.

It is well-settled that claims based upon a good faith interpretation of a disputed question of law do not violate the FCA because such claims are not objectively false. *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376-77 (4th Cir. 2008). FDA knew about the industry's longstanding practice of providing custom mixes without separate licenses, leading both Greer and the industry as a whole to believe that custom mixes were properly manufactured

under their existing general licenses.[5] (Mov. at 11-14). Accordingly, any claims for custom mixes would not be actionable under the FCA until FDA made its official position clear in its February 2015 draft guidance.[6] *Purcell*, 807 F.3d at 287 (defendant cannot be liable under FCA when first notice of incorrect interpretation of law came "long after the conduct giving rise" to case occurred).

Relators' attempt to scrutinize the industry's interpretation of the law does not diminish Greer's argument. In fact, Relators reinforce Greer's point by highlighting that different interpretations of the relevant regulations are possible. Relators simply cannot satisfy their burden of alleging objectively false claims where the entire industry and its regulator operated under a reasonable, alternative interpretation for over forty years.[7]

B. Relators Have Not Alleged That Greer Knowingly Submitted False Claims.

For the same reason, Relators have not sufficiently alleged that Greer *knowingly* submitted false claims. A defendant acts "knowingly" when it "(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." *United States ex rel. Harrison v. Westinghouse Savannah River Co.,* 352 F.3d 908, 917-18 (4th Cir. 2003). A party does not act knowingly when it "take[s] advantage of a disputed legal question." *United States ex rel. Hagood v. Sonoma Cty. Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991); *United States v.*

[5] FDA regulations and guidance promulgated *after* the enactment of § 610.17 indicate that FDA recognized (1) the validity of custom mixes, *see* 50 Fed. Reg. 3082, at 3107-08, 3283-85, (2) the distinction between custom mixes and named-patient prescriptions, *id.* at 3285, and (3) that manufacturers did not have separate licenses for custom mixes. (Mov. at 12-14).

[6] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434176.pdf.

[7] Greer's reading of 21 C.F.R. § 610.17 was objectively reasonable. Section 610.17 prohibits combinations of biological drug *products* without a separate license. The definitions set forth in FDA's 1999 Guidance (Ex. 13) supported the industry-wide belief that custom mixes were combinations of biological drug *substances*, and thus, not prohibited. *See* (Ex. 15) (Allergy Laboratories, a Greer competitor, manufactured custom mixes without separate licenses at the time it received the FDA Untitled Letter in May 2014).

Medica-Rents Co., 285 F. Supp. 2d 742, 772-75 (N.D. Tx. 2003). Against the backdrop of an industry-wide, decades long practice consistent with Greer's own practice that was transparent to FDA, and Greer's public advertising of its custom mixes, the only reasonable inference the Court can draw is that Greer believed it was acting properly. *Safeco Ins. Co. v. American Burr*, 551 U.S. 47, 69-71 (2007) (intent not established where party's reading of the "less-than-pellucid statutory text" was "not objectively unreasonable").

Relators' attempt to create an opposing inference is unavailing. Relators assert that they and FDA warned Greer that custom mixes were illegal "and yet [Greer] took affirmative steps to conceal its violations by misleadingly labelling its bulk custom mixes [with an 'RX' prefix] to appear as if they were sold by prescription." (Opp. at 18). Relators fail to present any evidence to support their baseless allegations. First, Relators' purported "warnings" are irrelevant to Relators' FCA claims.[8] Second, Relators' assertion that Greer added "RX" to the names of custom mixes, and that this action somehow proves Greer's knowledge of wrongdoing, is misleading. In fact, the only evidence of Greer using the term "RX" comes from Exhibit 1 – an *internal* and unauthenticated document.[9] Relators do not identify a single instance where FDA was shown a custom mix with the "RX" prefix or otherwise discussed the use of the prefix with anyone at Greer. (Ex. 11 at 2, 6) (FDA reviews "AASC Weed-1 Mix A" and "FAC Comprehensive Mix"). Relators admit that Greer manufactured custom mixes very publicly

[8] Am. Compl. at ¶ 82 (concerns about the licensure of Greer's *pharmacy*, which handles named-patient prescriptions (¶16)), ¶ 90 (issues involving manufacturing decisions involving retention samples), ¶ 89 ("untruthful" information "about the existence of the unopened kits" used in the SLIT trial), and ¶ 87 (alleged cGMP violations involving the SLIT trial). These allegations do not remotely suggest that Relators warned Greer that "its custom mixes were illegal."

[9] For each "RX" entry in Exhibit 1, a matching entry for the same mix appears without the "RX" prefix. Further, the "Sales Cod" column, which indicates whether an item is available for sale, says "NO" for the "RX" entries. Given that "RX" items cannot even be ordered for sale, it is unclear how Greer could have used that information to mislead anyone.

since at least 2001, when Greer advertised custom mixes on its website, (Am. Compl. at ¶¶ 54, 73), and do not allege that Greer otherwise tried to obscure the true approval status of its custom mixes or mislead FDA. Indeed, Relators all but concede that they do not have evidence to support this allegation in their Amended Complaint. (¶ 60) (alleging Greer used "RX" "*ostensibly* to create the illusion that the mixtures" were named-patient prescriptions). The absence of actual support for these conclusory allegations is fatal to Relators' claim.

III. Relators' Retaliation Claim Fails Because They Were Not Engaged in Protected Activity.

Relators' arguments in support of their retaliation claim warrant little discussion. As detailed in the Moving Brief, Relators cannot sustain a retaliation claim based on internal complaints about alleged regulatory and manufacturing issues that are unrelated to the submission of false claims for payment to the government. *Mann v. Heckler & Koch Def., Inc.*, 630 F.3d 338, 346 (4th Cir. 2010) ("'Correcting regulatory problems may be a laudable goal, but one not actionable under the FCA in the absence of actual fraudulent conduct'"). Because Relators do not identify the "nexus" between their internal reports and "exposing fraud or false claims," their retaliation claims fail. *United States ex rel. Brooks v. Lockheed Martin Corp.*, 423 F. Supp. 2d 522, 530 (D. Md. 2006).

IV. The Court Should Deny Relators' Request For Leave To Amend Because Any Amendment Would Be Futile.

Relators suggest three offers of proof that they will make should the Court agree that the Amended Complaint is deficient. First, Relators claim that they will "allege facts showing that when FDA inspectors asked Greer employees if they had prescriptions for custom mixtures with the 'RX' product names, the Greer employees replied in the affirmative." (Opp. at 3). Even assuming Relators could plead as much (which Greer seriously doubts), this "evidence" does not address their failure to identify specific claims for custom mixes. Second, Relators allege that

FDA inspectors were specifically "on the lookout" for the conduct alleged in the complaint during the November 2013 inspection, and later issued a Form 483 and Warning Letter. (Opp. at 23). These are simply facts in the chronology and do not change the legal analysis. Third, Relators' claim that there have been "material developments that have occurred since the complaint was originally filed," such as the FDA inspection, and the issuance of the Form 483 (Ex. 11), Warning Letter (Ex. 12), and Untitled Letters (Exs. 15 & 16), is misguided. Relators filed their Amended Complaint on May 9, 2014, almost six months *after* FDA inspected Greer's facility and issued the Form 483, and *after* FDA issued the Warning Letter. Although FDA issued the Untitled Letters after Relators filed the Amended Complaint, these letters do not correct Relators' numerous pleading deficiencies. Exhibit 15 merely suggests that until 2014, other manufacturers also believed that custom mixes were properly manufactured without a separate license. Additionally, Exhibit 16 makes Greer's point that FDA did not provide official notice that custom mixes required separate licenses until 2015. *Purcell*, 807 F.3d at 287. Because these allegations do not address, let alone cure, the deficiencies in the Amended Complaint, the Court should deny Relators' request for leave to amend as futile. *Wilson*, 525 F.3d at 376.

CONCLUSION

For the reasons set forth above and in the Moving Brief, Greer respectfully submits that the Amended Complaint should be dismissed, with prejudice, in its entirety.

Respectfully Submitted,

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